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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,720	02/15/2001	Klaus Abraham-Fuchs	P00,1222	2613

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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/11/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,720

Applicant(s)

ABRAHAM-FUCHS ET AL.

Examiner

Channing S. Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 3, filed 10 December 2002, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-16.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is applied as necessitated by amendment in Paper No. 10, filed December 2002.

Claims 1 (lines 27-29), 9 (lines 27-30), and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The introduction of "an expert system operating according to pre-existing expert rules...composed/compared to said pre-existing expert rules" in

Art Unit: 1631

newly amended claims 1 and 9 in Paper No. 3, filed 10 December 2002, is considered new matter. Support for amendments to claims 1 and 9 with regard to “pre-existing expert rules” could not be found throughout the specification. Therefore, the introduction of said “pre-existing expert rules” to be utilized in said network/method is considered NEW MATTER. Applicants are invited to particularly point out, page and line number, for support of the amendments to the instant claims.

LACK OF ENABLEMENT

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Applicants argue that “Expert systems, and the expert rules used in such expert systems, are so well known to those of ordinary skill in the art that no further explanation beyond that provided in the present specification is necessary...” in Paper No. 3, filed 10 December 2002, which is found unpersuasive.

The rejection of claims 1-16 is maintained under 35 U.S.C. § 112, first paragraph for reasons of record. While is acknowledged that “expert systems/rules” exist as stated by applicants (i.e. U.S. Patent No. 4,658,370) these references utilizing “expert systems/rules” provide for guidance as to the specific parameters/criteria/procedures of said systems and rules. For example, U.S. Patent No. 4,658,370 describes varying expert systems (i.e. MYCIN, EMYCIN, NEOMYCIN; Columns 2-4) wherein the expert systems maintain differing parameters/criteria/procedures for the utilization in medical diagnostics. Absent from applicants specification is guidance as to the specific parameter/criteria/procedures for the application of the “expert systems/rules” utilized in the instantly claimed invention. Thus, reiterated from the previous office action Paper No. 2, mailed 10 September 2002, said “missing steps/procedures are essential to the use of the invention as claimed and therefore one of skill in the art cannot use the invention with the amount and direction presented, is therefore unpredictable, and would require undue experimentation”.

Applicants disclosure states “The present invention makes use of currently available biosensor arrays (biochips) and Electronic Patient Records (EPR)” (page 4, lines 14-15), however, the specification fails to indicate the particular markers to be utilized on the biochip, the particular sample to be utilized on the biochip, nor the information to be collected in for the electronic patient records. The disclosure states biochips that are “about to enter widespread

Art Unit: 1631

use”, which does not mean said biochips would have been readily available to practice the claimed invention (page 4, lines 16-17 of the Specification). No example is provided for in the specification that would allow one of skill in the art to perform the instant claimed invention; lacking is any electronic patient record, any data analyzed, compiled clinical study for the formulation of a new expert rule, etc. Additionally, the specification fails to identify a known expert system with pre-existing rules that can be used to solve problem at hand, wherein no problem is identified. Failure of such guidance is an invitation to experiment and develop an expert system, thus requiring undue experimentation. Therefore, absent from the specification is any direction on how to specifically analyze data (markers, disease, other parameters).

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-16 are maintained under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 1 (lines 26-27), 9 (line 25); and all claims dependent therefrom recites the phrase “improved diagnostic utility” which is vague and indefinite. It is unclear as to the metes and bounds by which applicants assert “diagnostic utility”, however, applicants can resolve this issue by particularly pointing out the limitations which encompasses said “diagnostic utility” with regard to improved diagnostic. Clarification of the metes and bounds, via clearer claim language, is required.

Art Unit: 1631

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *March 9, 2003*

Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
41151